

## **Summary of the Meeting of the Environmental Laboratory Advisory Board January 14, 1999**

The Environmental Laboratory Advisory Board (ELAB) met on Thursday, January 14, 1999 from 8:30 a.m. to 12:30 p.m. Eastern Standard Time (EST) following the Fourth NELAC Interim Meeting in Bethesda, Maryland. The meeting was led by its Co-Chairs, Dr. Wilson Hershey and Ms. Ramona Trovato. A list of action items is given in Attachment A. Meeting participants are listed in Attachment B. The meeting agenda is provided in Attachment C.

### **INTRODUCTION**

Dr. Hershey opened the meeting by introducing Ms. Elizabeth Dutrow, the Designated Federal Officer. Ms. Dutrow summarized the meeting rules, reminding participants that this meeting is open to the public and that minutes would be posted to the ELAB page on the NELAC web site.

### **ELAB PBMS WORKGROUP**

ELAB established a performance-based measurement systems (PBMS) workgroup at the July 1, 1998 meeting of ELAB. Mr. Jerry Parr, Chair, presented the workgroup's January 4, 1999 final report to ELAB. He reviewed the executive summary, outlining the primary activities performed by the workgroup, highlighting the "Critical Elements" and "Other Essential Elements" which the workgroup identified as essential to the successful implementation of a PBMS. He then reviewed the four recommendations the workgroup made to ELAB.

Mr. Parr was asked to summarize his findings from a review of 650 EPA methods; he noted that only 28% of them had published statements of precision, bias, and sensitivity. The remainder did not. Mr. Parr noted the workgroup did consider the topic of grandfathering in the existing EPA methods (ELAB recommendation from 12/10/98 conference call) but decided against this recommendation as the workgroup believes all EPA methods should have statements of expected method performance. Mr. Parr related that the workgroup does not believe EPA must necessarily go back and perform interlaboratory validation studies on all of the existing EPA methods, because suitable data can likely be obtained from the results of existing proficiency testing studies. This existing data could be gathered, analyzed and included in the methods.

Mr. Parr was asked to review his finding from a review of 650 EPA methods, he noted that 28% of them had validation data that could be located. The remainder did not. Mr. Parr noted the workgroup considered the topic of grandfathering existing methods and decided against it at this time but to include a discussion of the merits of a successful PBMS program. Mr. Parr related that the ELAB workgroup had considered suggesting that EPA and its individual laboratories validate the existing EPA methods but that the workgroup felt that for all of these methods, validation data must exist in the results of proficiency evaluation studies and should be gathered, analyzed, and included in the methods.

The ELAB members then discussed the report. One person suggested changing the term "customer needs" to "data use" on page 7. Another suggestion was made to delete the word "unlimited" from B-1. The idea was offered that the report could address regulatory issues related to validation (i.e., what is required with validation).

Public comments received:

- Define DQO/MQO.
- A reference method needs to be identified as the starting point for validating a method. (Mr. Parr responded that a reference method is only one way to validate a method and that analysis of reference materials and interlaboratory studies may also be used to accomplish this.)
- It was suggested that “Documentation” become a critical element.
- A-5 - last italicized sentence - is ill-timed - The wording “no later than concurrent with new regulation” was suggested.
- B-1 - A commenter suggested change should be made with the knowledge of the client.
- In regard to Recommendation 4, Dr. Ken Jackson, Chair of NELAC Board of Directors, stated that NELAC has worked to address PBMS in the standards and has made a firm commitment to PBMS.
- A commenter suggested defining the data need of the customer. If the need cannot be defined in data quality objectives, then the data should not be collected.

Final discussion among the ELAB members noted that a previous PBMS report prepared by Kathy Hillig concluded that regulatory issues relative to validation need to be addressed. Further, “documented” was added to A-1, 2) prior to “statements of method performance”.

Following discussion, it was moved, seconded, and unanimously approved that:

- ELAB accept the report of the PBMS workgroup as a product of ELAB with the incorporation of previous findings and minor editorial changes. It was decided that a formal ELAB report will be sent by ELAB to EPA with an appropriate cover letter introducing the document and its issues.

## **ELAB SMALL LABORATORY WORKGROUP**

This workgroup was established at the July 1, 1998 meeting of ELAB to address concerns of small laboratories with regard to NELAC implementation. Ms. Evelyn Torres, Co-Chair, explained ELAB sought comment from the small laboratory community. The common concern expressed by 12 commentors was a fear that NELAC standards will add to the cost of operation for small laboratories.

Board members expressed the concern that the nature of some commenter’s remarks may indicate a misunderstanding of the NELAC standards. It was suggested that NELAC could be asked to develop a set of frequently asked questions to address small laboratory concerns and that specific issues could be forwarded to relevant NELAC committees (specifically the NELAC Membership & Outreach Committee could help in this regard). Support was heard in ELAB for the idea of NELAC being proactive in reaching out to small labs. State laboratory associations were suggested as one means for communicating with small laboratories. Members suggested providing start-up materials (i.e., models for documentation, standard operating procedures, etc.) for small laboratories through the NELAC web page was a good idea.

Public comments received:

- The issues of small laboratories are the issues of all laboratories.
- The States of New York, Oregon, and Kansas spoke on their outreach to the small laboratories. New York mentioned many small laboratories already participate in its accreditation program. The remaining States noted that small laboratories do not want to be different from larger firms. Also, one State noted that it has never differentiated between small and large laboratories in its program.

- Support was voiced for development of a toolkit containing model documents, case histories, and so forth to assist small laboratories. It was noted that development and documentation of a quality system is a significant task for any organization to undertake.
- It was noted that during the FIFRA Good Laboratory Practices program startup, there was similar support for small laboratories. It was also noted that Florida already provides outreach support which may be accessed at <http://www.dep.state.fl.us/labs/>.
- Dr. Ken Jackson, NELAC Chair, noted that NELAC is extremely sensitive to this issue, and continues to address it in developing the NELAC standards. He noted that NELAC committees are in the process of addressing comments contained in an extensive, detailed submittal by the Virginia Small Laboratories association. On behalf of NELAC, Dr. Jackson welcomed comments from ELAB on the matter of small laboratories.
- Several commenters noted it is important that the NELAC standards address only issues essential to achieving an acceptable level of data quality.

ELAB continued its discussion. Since small laboratory issues continue to be of concern, it was suggested that the agenda for future ELAB meetings have this issue as a standing agenda item. Following discussion, it was moved, seconded, and unanimously approved that ELAB recommend that:

- NELAC reach out to laboratory associations through its web page by providing relevant links and sample standard operating procedures, case histories, sample quality manuals, and work sheets to assist small laboratories;
- ELAB ensure a flow of information and guidance to the NELAC Committees by submitting significant information on to the NELAC Membership and Outreach Committee;
- NELAC continue to ensure that the NELAC standards contain only essentials to achieve the desired data quality; and,
- ELAB make small laboratory issues a standing agenda item for future ELAB meetings.

### **THIRD PARTY ASSESSORS WORKGROUP**

This workgroup was established at the July 1, 1998 meeting of ELAB to address minimum credentials for third-party assessors, both for individuals and organizations. Ms. Sandra Wroblewski, Co-Chair, reported that additional members are needed in the workgroup, and that the first meeting of this group is scheduled for early March. The workgroup requested that two State representatives join it. It was requested that one representative be from a State that will use third party assessors and that the other represent a State not using third party assessors.

Agreed upon action item:

This issue will remain on the agenda for the ELAB meeting in conjunction with NELAC V in June 1999.

### **FIELD MEASUREMENTS ISSUES**

In the absence of Dr. Barton Simmons, Chair of the NELAC Field Measurements *ad hoc* Committee, Dr. Hershey reviewed for the Board issues discussed with Dr. Simmons during ELAB's December 10, 1998 meeting. He noted that the *ad hoc* committee is continuing with its study of the issue of field measurements, anticipating that the *ad hoc* committee soon will be converted to a NELAC standing committee. Dr. Hershey related that the matter of how to address field sampling is not as well defined and

that the *ad hoc* committee is collecting information on relevant matters such as stakeholders and their needs.

Several Board members noted that careful definition of field measurement components (i.e., field laboratories, mobile laboratories, and field measurements) is essential with the rapidly increasing need for acceptable field measurements. One member noted it would be prudent to hold on further discussion of mobile laboratories in the NELAC Accreditation Process Committee until further work is done on the definition of such a laboratory.

Public comment received:

- A definition of field measurements is needed; the commenter noted a concern over the loss in the quality of work if a temporary “lab on wheels” is away from the parent laboratory for too long.
- On-line monitors generate more data than mobile or stationary laboratories; commenter did not believe ELAB wanted to get involved with on-line monitoring.
- NELAC Field Measurements and Accreditation Process Committees must work together.

Following discussion, it was moved, seconded and unanimously approved that ELAB recommend that:

- the NELAC Accreditation Process and Field Measurements Committees work together to develop a clear definition of critical terms (i.e., field laboratory, mobile laboratory, field measurement, and fixed laboratory) prior to defining the accreditation process for other than fixed laboratories; and,
- ELAB exclude on-line monitors from its consideration.

## **STATUS OF RECOMMENDATIONS TO EPA**

Dr. Hershey reviewed previous action items and recommendations to EPA. He noted that the response from Ms. Carol Finch of EPA’s Environmental Monitoring Management Council had just been received and was included in the ELAB handout materials for later review. He also noted that he met with Dr. Norine Noonan, the newly-appointed Assistant Administrator for EPA’s Office of Research and Development and discussed the EPA-Department of Transportation (DOT) issue of sample pH, PBMS, and the need for methods to be available when new regulations are promulgated. He noted that Dr. Noonan had expressed interest in ELAB’s counsel on implementation of the PBMS approach and had committed the EMMC staff to address the conflict between EPA and DOT regulations.

Agreed upon action items include:

- Dr. Hershey announced that a meeting of ELAB by teleconference will be scheduled in roughly 6 weeks to review the status of recommendations and action items from past meetings.
- A standing item will be added to each agenda for future meetings of ELAB to address the status of ELAB recommendations and to determine what further action ELAB should take on outstanding issues.
- A listing and status of ELAB recommendations will be added to the ELAB site on the NELAC web page.

## **REVIEW OF STANDARDS AS DISCUSSED AT NELAC IVi**

Dr. Hershey began this discussion by reminding the Board that the impending elevation of ISO Guide 25 to the level of ISO Standard 17025 will have implications for the NELAC standards.

### **Proficiency Testing Samples**

An ELAB member requested a summary of the proficiency testing (PT) events of NELAC IVi. ELAB invited those in the audience familiar with the PT Committee meeting to summarize its events. Ms. Lara Autry and Ms. Darlene Raiford, both members of the PT Committee, reviewed the PT discussions which occurred during NELAC IVi.

Dr. Ken Jackson, NELAC Chair, communicated the NELAC Board's position that there is an urgent need for proficiency testing samples in solid waste and air matrices. He noted that the present contractual arrangements between NIST and EPA respond to the externalization of EPA's WS and WP series of samples which address only a limited suite of analytes in water (drinking water and industrial effluent).

An ELAB member noted that PBMS will not be successful without good PT samples.

Additional comments from the public were received. A representative from the National Institute of Standards & Technology stated that there is a need for guidelines and user-defined constraints for preparation of other samples. This representative asked what the criteria are for other matrices.

Following further discussion, it was moved, seconded and unanimously approved that

- ELAB believes the current EPA proficiency testing program for water is unacceptably limited. ELAB recommends that EPA act quickly to broaden the availability of proficiency testing samples for matrices other than water (e.g. solid waste, air, tissue, etc.)

### **Implementation of NELAC Standards**

The NELAC standards are approved in voting sessions during the Annual meeting. It was noted that there is presently no specification for when the newly approved standards become effective. This presents difficulties for many NELAC stakeholders (legislatures, regulators, accrediting authorities, and laboratories) due to the differing lead-times needed to comply with the new standards. Discussion also centered on the use of the 1999 standards as the version that the first class of accredited laboratories should have to meet. It was suggested that laboratory applications for entrance in the first class of laboratories should be accepted through July 1999. Then, one year should be allowed to meet the new standards. It was suggested a one year shift to announce the first class in July 2000 should occur to accommodate acceptance of applications through July 1999.

Public comments received:

- States need time to change their regulations.
- States are being assessed according to the 1997 standards.
- Do not accept applications until after NELAC V so that laboratories will know what standards to meet.
- Laboratories do not wish to be penalized if they meet the newest NELAC standards.

Following discussion it was moved, seconded, and unanimously approved that:

- ELAB recommend to NELAC that
  - a) the NELAC standards become effective and enforceable one year after adoption, and
  - b) that for the first group of laboratories to be accredited under NELAC standards, the 1999 standards be used for compliance and that the related timelines for acceptance of applications be adjusted accordingly.

### **Open Forum Issues**

A list of issues raised during the ELAB Open Forum on Wednesday, January 13, 1999 were distributed to the Board. The Board agreed many of the most pressing issues on this listing had been addressed. Dr. Hershey asked the Board to review those remaining issues and be prepared to discuss them in their next meeting.

Items identified during the Open Forum include:

- NIST oversight of PT providers - Does NIST plan to notify Accrediting Authorities of failed rounds?
- NELAC Regulatory Coordination Committee requested clear delineation of test methods and analytes, per Figure 1-3 of the NELAC standards; spreadsheets were offered as assistance.
- Where does the matter of sample preservation and shipment stand (EPA-DOT)?
- Consistency of assessments when multiple accrediting authorities and assessors are used
- Clarification of calibration issues
- NIST role in the PT program with respect to the NELAC PT requirements
- Identity of PTOB/PTPA in NELAC Chapter 2
- Clarification of field measurements versus laboratory measurements for short holding times (<15 minutes)
- Harmonization of NELAC standards and EPA's Quality Assurance Division's guidance
- Clarification of field laboratories, mobile laboratories, field measurements, etc. Assistance to the Accreditation Process Committee was requested.
- PBMS
- Confidentiality with respect to the use of State laboratory staff on assessment teams for private laboratories
- On-site Assessment Committee needs to accelerate its activity
- NELAC Standard milestones are needed (effective dates for standards, dates for application to accrediting authorities, etc.)

**ACTION ITEMS**  
**Environmental Laboratory Advisory Board Meeting**  
**January 14, 1999**

<b>Item No.</b>	<b>Action Item</b>	<b>Date To Be Completed</b>
1.	Members are to review past action items for discussion at the next ELAB meeting and determine what further action to take.	3/1/99
2.	Members are to review issues from the Open Forum for discussion at the next ELAB Meeting.	3/1/99
3.	Mr. Parr will revise the PBMS report to ELAB, incorporating previous comments.	2/5/99
4.	Dr. Hershey to prepare letter of transmittal for PBMS report to EPA and submit report.	2/99
5.	ELAB to recommend to NELAC that -NELAC assist small laboratories by developing support materials and including materials on web page, -NELAC include only essential elements in the standards, -NELAC's Field Measurements and Accreditation Process Committees develop working definitions for field operations, and -NELAC define effective dates for new standards.	2/99
6.	ELAB will make the small laboratories issue a standing agenda item.	ongoing
7.	Third-party assessors work group will be on the agenda for the June 1999 meeting of ELAB	6/99
8.	ELAB will make a status review of previous recommendations a standing agenda item.	ongoing
9.	ELAB will communicate to EPA its belief that the current PT program is unacceptable and needs to be expanded.	3/99

**PARTICIPANTS**  
**Environmental Laboratory Advisory Board Meeting**  
**January 14, 1999**

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## **ENVIRONMENTAL LABORATORY ADVISORY BOARD**

### **Meeting Agenda**

**8:30 am - 12:30 pm**

**January 14, 1999**

**Hyatt Regency Bethesda**

**Bethesda, Maryland**

8:30 am - 8:40 am	Introduction of Board; Review of Meeting Rules	Elizabeth Dutrow, Designated Federal Officer
8:40 am - 8:50 am	Welcome and Review of Agenda	Wilson Hershey, Co-Chair
8:50 am - 9:50 am	Report from ELAB PBMS Workgroup	Jerry Parr
9:50 am - 10:15 am	Report from ELAB Small Laboratory Workgroup	Evelyn Torres
10:15 am - 10:30 am	BREAK	
10:30 am - 10:50 am	Third Party Assessors Workgroup Update	Sandra Wroblewski, William Kavanaugh
10:50 am - 11:05 am	Field Measurement Issues	Wilson Hershey
11:05 am - 11:20 am	Status of Recommendations to EPA	Wilson Hershey
11:20 am - 11:40 am	Review of Standards as Discussed at NELAC IVi	Wilson Hershey
11:40 am - 12:00 pm	Open Forum Issues	Ramona Trovato, Co-Chair
12:00 pm - 12:30 am	Action Items; Closure	Ramona Trovato, Wilson Hershey